Supreme Court, U.S
FILED
SEP 10 1993
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No. 93-220

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1993

DUPHAR, B.V.,
Petitioner

v.

KATHY TOBIN,
Respondent

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1) Is a foreign manufacturer which creates and employs a distribution scheme wherein the United States distributor is required to market a product in the forum state subject to personal jurisdiction in the forum in which the product was sold, used and caused Plaintiff's injury?

2) Is a foreign manufacturer which comes to the United States to conduct clinical trials of its drug in order to gain FDA approval and then retains control over the subsequent sale and the inadequate warning inserted in the package subject to personal jurisdiction in the forum in which the product was sold, used and caused Plaintiff's injury?

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TABLE OF CASES AND AUTHORITIES

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Statutes Cited

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STATEMENT OF THE CASE

In March of 1979, Duphar filed its New Drug Application ("NDA") for ritodrine with the United States Food and Drug Administration ("FDA") pursuant to 21 U.S.C. § 355. Duphar sought and received FDA approval for marketing ritodrine in "interstate commerce" within the United States. 21 U.S.C. § 355(a).

Duphar manufactures the oral ritodrine prescribed to Kathy Tobin in tablet form and ships it in bulk to Astra. Astra distributes it directly to retail outlets throughout the United States.

The only warning provided with ritodrine is the package insert. The content of the warnings therein is submitted by the NDA applicant (Duphar). The jury below found this warning inadequate. The agreement between Duphar and Astra provided:

> ASTRA will regularly consult with DUPHAR as to its dealings with the FDA and obtain DUPHAR'S advice *and agreement* (such agreement not to be unreasonably delayed or withheld by DUPHAR) prior to submitting to the FDA any information on the Product, *its labeling, package inserts or otherwise.* [emphasis added] (See Petitioner's Appendix, p. E24).

Duphar has expressly licensed Astra to sell ritodrine in the forum.[1]

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[1] Astra's "Territory" is designated as "the United States of America, its territories and possessions, and Puerto Rico." (See Petitioner's Appendix, pp. E23-E24).

REASONS FOR DENYING WRIT

I.

The Issues Presented are Moot Because the Judgment Below has been Paid and the Time for a Petition for Writ as to Liability has Run.

Astra Pharmaceuticals has paid the judgment entered herein and has not applied for *certiorari*. The time for a Petition for *Certiorari* on any liability issue has run. Therefore, any decision rendered upon the issues presented herein will not affect the parties and the Petition is in the nature of a request for an advisory opinion.

II

There is No Conflict Between the Circuits and the Decision Below was Correct Under This Court's Precedent and the Facts of this Case.

Duphar's Petition does not assert a conflict between the circuits, apparently only alleging that the issues were wrongly decided below and are of sufficient

importance to warrant the Court's attention. While Respondent agrees the issues are academically important, they are not important in the context of this case--the judgment being satisfied and not appealed. Even if abstractly important, the issues presented herein were decided correctly below.

In Asahi Metal Ind. v. Super. Ct. of Cal., Solano Cty., 480 U.S. 102 (1987) Justice O'Connor's plurality opinion held that jurisdiction did not lie because the defendant did not "create, control, or employ the distribution system which brought the product to [the forum]." [emphasis added] Id., 480 U.S. at 112-13.

In the case *sub judice*, The Sixth Circuit correctly held Duphar subject to personal jurisdiction because it created, controlled and employed the distribution scheme which brought ritodrine to the forum. Tobin v. Astra Pharmaceutical

Products, Inc., 993 F.2d 528 (6th Cir. 1993)(Petitioner's Appendix E23-E24). Even the district court acknowledged that Duphar employed the distribution scheme which brought ritodrine to the forum. (Petitioner's Appendix, A6).

Duphar's belief that the decision below is based upon "national contacts" or a "stream of commerce" theory thereby doing damage to Due Process and federalism arises from its misunderstanding of the national contacts and stream of commerce concepts. Duphar's conduct in this case is *not* analogous to defendants in Asahi, supra, and other stream of commerce cases. Duphar did *not* simply place its product in a stream of commerce which haphazardly swept it to the forum. Duphar formally entered into an elaborate licensing agreement with Astra providing that Astra would distribute ritodrine in "the United States of America, its territories and

possessions, and Puerto Rico." Such an agreement would have been no different if it had listed each of the fifty states by name: it is a deliberate decision to market ritodrine in the forum state. Moreover, Duphar formally retained control over the content of the warning which accompanies its product in every sale to every purchaser in every state. Clearly, due process is satisfied by such purposeful availment of the market of the forum state.

CONCLUSION

For the reasons stated above this petition should be denied.

Respectfully submitted,

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